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NOTICE OF ALLOWANCE AND FEE(S) DUE

66482

7590

12/02/2009

Law Offices of Tim Headley
7941 Katy Fwy, Suite 506
Houston, TX 77024-1924

EXAMINER

OSTRUP, CLINTON T

ART UNIT

PAPER NUMBER

3771

DATE MAILED: 12/02/2009

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,110	12/27/2005	David Peter Wharton	130098-1001	3572

TITLE OF INVENTION: DRUG DELIVERY DEVICE AND METHOD

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$755	\$300	\$0	\$1055	03/02/2010

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. **PROSECUTION ON THE MERITS IS CLOSED.** THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN **THREE MONTHS** FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. **THIS STATUTORY PERIOD CANNOT BE EXTENDED.** SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
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INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

66482 7590 12/02/2009

Law Offices of Tim Headley
 7941 Katy Fwy, Suite 506
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I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

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nonprovisional	YES	\$755	\$300	\$0	\$1055	03/02/2010

EXAMINER	ART UNIT	CLASS-SUBCLASS
OSTRUP, CLINTON T	3771	128-201220

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB-122) attached.
☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB-47; Rev 03-02 or more recent) attached. Use of a **Customer Number is required.**

2. For printing on the patent front page, list

- (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, 1 _____
 (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 2 _____
 3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
☐ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
☐ Payment by credit card. Form PTO-2038 is attached.
☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date _____
 Typed or printed name _____ Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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			ART UNIT	PAPER NUMBER

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DATE MAILED: 12/02/2009

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 876 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 876 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Notice of Allowability**Application No.**

10/535,110

Applicant(s)

WHARTON ET AL.

Examiner

CLINTON OSTRUP

Art Unit

3771

- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment filed 8/21/09, the IDS filed 11/12/09 and the telephonic interview 11/17/09.

2. ☒ The allowed claim(s) is/are 1, 2, 4, 5-15, 17, 22-23, 25, 27, 29-31, 33-34, 39, 42, 44, 54, 60.

3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of the:

1. ☒ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. ____.

3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: ____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.

(a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached

1) ☐ hereto or 2) ☐ to Paper No./Mail Date ____.

(b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date ____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)

2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3. ☒ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date 11/12/09 & 11/17/05

4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material

5. ☐ Notice of Informal Patent Application

6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date ____.

7. ☒ Examiner's Amendment/Comment

8. ☒ Examiner's Statement of Reasons for Allowance

9. ☐ Other ____.

/Steven O. Douglas/
Primary Examiner, Art Unit 3771

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.
2. Authorization for this examiner's amendment was given in a telephone interview with Tim Headley on November 17, 2009.
3. The application has been amended as follows:

Claim 1. (Currently amended) A modified breathing apparatus for medicating an air stream, said modified breathing apparatus comprising:

- ~~a-~~ a) a breathing apparatus including a regulator suitable for delivering air from a source of compressed air, the regulator adapted for use in at least one of scuba gear, aircraft applications, gas masks, hazardous environments, mountaineering, power assisted respirators and other similar applications, and a self-contained breathing apparatus;
- ~~b-~~ b) a medication chamber adapted to store and discharge a therapeutic agent;
- ~~c-~~ c) a delivery pathway between the chamber and an intake air pathway of the breathing apparatus; and
- ~~d-~~ d) a releasing means for selectively discharging the therapeutic agent from the chamber into the intake air pathway through the delivery pathway.

Claim 4. (Currently amended) The modified breathing apparatus of claim 1 wherein the breathing apparatus is a self-contained breathing apparatus (~~"SCBA"~~) (SCBA) suitable for use in firefighting and rescue, industry, shipping, mining, mountaineering, hazardous environment, aircraft and/or conditions of higher or lower atmospheric pressure.

Claim 6. (Currently amended) The modified breathing apparatus of claim 5, wherein the therapeutic agent is housed in a container, said container adapted to be located in the medication chamber.

Claim 9. (Currently amended) The modified breathing apparatus of claim 2 further comprising a balance means for substantially equalizing pressure in the chamber with ambient pressure.

Claim 13. (Currently amended) The modified breathing apparatus of claim 6 wherein the container comprises a capsule, a vial, a gelatine capsule or a blister pack.

Claim 16 has been cancelled.

Claim 17. (Currently amended) The modified breathing apparatus of claim 15 wherein the delivery pathway includes valve means operable to open and close the bore, channel or aperture. [[.]]

Claim 22. (Currently amended) The modified breathing apparatus of claim 10 wherein the releasing means comprises a rotatable control for activating a displacement mechanism to displace one of the pressurized canister and a seat co-operating with the canister and thereby activate the release valve of the pressurized canister. [[.]]

Claim 27. (Currently amended) The modified breathing apparatus ~~of either of claims claim 17 or 19~~ wherein depression of the pressure activated button or rotation of the rotatable control rotates a delivery chute into a discharge position from an inactive position. [[.]]

Claim 29. (Currently amended) The modified breathing apparatus of claim 1 further including counting means for indicating, ~~at least approximately,~~ the number of doses of therapeutic agent that have been discharged from the medication chamber.

Claim 33. (Currently amended) A medication chamber for use in medicating an air stream, the medication chamber comprising:

- a- a) an outer housing defining an internal chamber containing a therapeutic agent;
- b- b) mounting means for fixing the medication chamber to an air channelling device, said air channelling device comprising a regulator adapted for use in scuba gear, aircraft applications, gas masks, hazardous environments, mountaineering, power

~~assisted respirators and other similar applications;~~

~~e- c)~~ at least one delivery path from the internal chamber externally and adapted to deliver the therapeutic agent to an air pathway in the air channelling device; and
~~d) a~~ releasing means for releasing the therapeutic agent from the internal chamber.

Claim 34. (Currently amended) The medication chamber of claim 33 including one or more of:

- ~~a- a)~~ the outer housing ~ formed of metal, plastic or polyvinyl chloride;
- ~~b- b)~~ the internal chamber sealed to resist entry of water, mud, dust or other contaminants;
- ~~c- c)~~ the outer housing formed as two inter-engageable sections;
- ~~d- d)~~ the therapeutic agent being any one of more of salbutamol, beconase, adrenaline, aminophylline or glucose;
- ~~e- e)~~ the outer housing including an inlet pathway for receiving a pressurized air supply into the internal chamber; and
- ~~f- f)~~ the outer housing including an outlet valve for discharging air from the internal chamber when air pressure inside the chamber exceeds the pressure outside the internal chamber.

Claim 54. (Currently amended) A method of medicating an air stream in a breathing apparatus comprising a regulator suitable for delivering air from a source of compressed

air, the regulator adapted for use in at least one of scuba gear, aircraft applications, gas masks, hazardous environments, mountaineering, power assisted respirators ~~and other similar applications~~, and a self-contained breathing apparatus, the method comprising the steps of mounting a chamber containing a therapeutic agent to a breathing apparatus and introducing one or more doses of the therapeutic agent into an inlet pathway for inspiratory air.

Reasons for Allowance

4. The following is an examiner's statement of reasons for allowance: The closest prior art, Botos et al., (4,031,887) discloses an under water breathing apparatus (figure 1) with a fresh gas container (10) and a dosing bottle (18). However, although the dosing bottle (18) can store and discharge a therapeutic agent (gas) it lacks a releasing means for selectively discharging the therapeutic agent from the medication chamber. Greenfield (3,490,452) teaches a mask (10) with an oxygen supply (100) and a medication chamber (32) that is adapted discharge a therapeutic agent (inside 70) with a releasing means for discharging the therapeutic agent into the chamber and then into the intake air pathway through the delivery pathway.
5. However, neither of the references teaches or fairly suggests utilizing a breathing apparatus comprising a breathing apparatus including a regulator suitable for delivering air from a source of compressed air, the regulator adapted for use in at least one of scuba gear, aircraft applications, gas masks, hazardous environments, mountaineering, power assisted respirators, and a self-contained breathing apparatus, wherein the

releasing means for selectively discharging the therapeutic agent from the chamber into the intake air pathway through the delivery pathway. Moreover, Botos is used to deliver gas to persons in under water applications whereas Greenfield is used as nebulization therapy for patients suffering from pulmonary diseases and disorders. Since persons with pulmonary diseases, dysfunction, and disorders are typically dissuaded from practicing scuba diving and other under water breathing activities, because of the contraindications associated therewith, one skill in the art would not have reasonably combined Botos with Greenfield to arrive at the applicant's claimed invention.

Thus, the combination of Botos with Greenfield to arrive at applicant's claimed invention could only be construed as improper hindsight reasoning.

6. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Bowden (7,207,329); Fitton (2003/0150450); Curtin (4,304,229) and Mansson et al. (5,318,015) which teach gas delivery devices using mouthpieces.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CLINTON OSTRUP whose telephone number is (571)272-5559. The examiner can normally be reached on Monday-Friday.

9. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.
10. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Clinton Ostrup/
Examiner, Art Unit 3771

/Steven O. Douglas/
Primary Examiner, Art Unit 3771